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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,749	07/11/2001	Avi Ashkenazi	10466/43	5380

30313 7590 09/26/2003

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/26/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/903,749

Applicant(s)

ASHKENAZI ET AL.

Examiner

Olga N. Chernyshev

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Claim 39 has been amended and claim 44 has been cancelled as requested in the amendment of Paper No. 19, filed on July 23, 2003. Claims 39-43 are pending in the instant application.

Claims 39-43 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on July 23, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Priority

5. Applicant's arguments regarding the effective filing date of the instant application are fully answered in section 8 of the instant office action below.

Claim Rejections - 35 USC § 112

6. Claims 39-43 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for those reasons of record in section 7 of Paper No. 18. Briefly, claims 39-43 are

Art Unit: 1646

directed to an antibody that binds specifically to the polypeptide of SEQ ID NO: 2, and the instant specification, as filed, fails to describe an antibody that specifically binds to a polypeptide of SEQ ID NO: 2 to the exclusion of binding to any other protein, for example, other human proteins or other proteins in general. Applicant traverses the rejection on the premise that “[i]t is well known to those skilled in the art that antibodies are generally defined in terms of their specific binding to a particular antigen” (page 5, last paragraph of the Response). This argument has been fully considered but is not deemed to be persuasive because the instant specification, as filed, does not provide adequate enablement on how to generate an antibody that binds exclusively to the polypeptide of SEQ ID NO: 2 and does not bind any other polypeptide, such as a human polypeptide which shares sequence similarity with SEQ ID NO: 2. While there is no argument that “one of ordinary skill [is able] to make antibodies that” bind to a polypeptide of SEQ ID NO: 2 (page 6, first paragraph of the Response), one would not know how to distinguish the antibodies that “bind” to a polypeptide of SEQ ID NO: 2 and those that “specifically bind” to a polypeptide of SEQ ID NO: 2. Therefore, one would reasonably conclude that it would require undue experimentation on part of a skilled artisan to create an antibody that “binds specifically to the polypeptide of SEQ ID NO: 2” of the instant invention.

7. Claims 39-43 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record in section 8 of Paper No. 18. Applicant submits a statement that “the art-recognized meaning of “specific” binding is that the antibody binds specifically to a particular antigen and does not significantly cross-react with another antigen” (page 6, fourth paragraph of the Response). This is not deemed to be persuasive because it is not

Art Unit: 1646

clear what additional limitation the recitation "specifically binds to" adds to the claimed subject matter. Applicant is advised that using recitation "an isolated antibody that binds to the polypeptide" would obviate this ground of rejection.

Claim Rejections - 35 USC § 102

8. Claims 39-43 stand rejected under 35 U.S.C. 102(a) as being anticipated by WO99/58660 for those reasons of record in section 7 of Paper No. 13. Briefly, because the effective filing date of the instant application is awarded as 2/22/2000, WO99/58660 document is considered to be 102(a) art.

Applicant presents arguments that the Examiner has failed to provide any explanation why Dr. Goddard's declaration and gene amplification data are insufficient to establish the practical utility of the instant invention (page 3-4 of the Response). Applicant submits that "since the gene amplification results first disclosed in application PCT/US98/18824 establish a specific and credible asserted utility for the anti-PRO-211 antibodies claimed" then the effective priority date of the instant specification should be awarded as 09/10/1998 (page 4 of the Response).

Applicant's arguments have been considered but are not deemed to be persuasive for the following reasons. The Declaration of Goddard supplies information regarding an amplification assay utilizing genomic DNA samples from primary tumors and tumor cell lines, wherein the significant amplification of DNA sequence of PRO211 was detected in lung and colon tumors. Therefore, based on the data provided, it was asserted that PRO211 polypeptide and, consequently, an antibody to PRO211, have utility as a marker for lung and colon cancer.

However, the increased copy number of DNA does not provide a readily apparent use for the

Art Unit: 1646

polypeptide PRO211 itself, for which there is no information regarding level of expression, biological activity or a specific role in lung or colon cancer, as disclosed. Based on the instant disclosure, one skilled in the art would clearly not be able to use the instant PRO211 polypeptide, or an antibody to PRO211 to distinguish between normal and cancerous tissue because there is no disclosure regarding point of reference of the expression of PRO211 in normal cells compared to cancer cells. Therefore, it was concluded that the only specific and credible substantial utility of the antibody to PRO211 polypeptide is based on the utility of the PRO211 polypeptide itself, which was established based on ability of PRO211 to inhibit VEGF stimulated proliferation of adrenal cortical capillary endothelial cells, which was first disclosed in application PCT/US00/04414, filed on 2/22/2000.

Conclusion

9. No claim is allowed.
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1646

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Art Unit: 1646

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
September 25, 2003



JOHN ULM
PRIMARY EXAMINER
GROUP 1800